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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,800	09/12/2005	Esteban Celis	07039-407US1	8961

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EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	
MAIL DATE	**DELIVERY MODE**
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,800	CELIS, ESTEBAN	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Nov 7, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-15 are pending and under examination. Claims 16-52 have been canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (WO 01/12215, Pub Date February 22, 2001) in view of Moss et al. (WO 95/24925, Pub Date September 21, 1995).

The claimed invention is drawn to a method for eliciting an immune response against EBV comprising; (a) identifying a subject in need of vaccination against EBV, wherein said subject express one or more HLA class II molecules: HLA-DR1, HLA-DR7, HLA-DR16, HLA-DR52, HLA-DQ2 or HLA-DQ7; (b) administering to said subject an EBV peptide epitope having the amino acid sequence SEQ ID NO: 1; and (c) administering to said subject one or more immune-enhancing agents, wherein one or more immune-enhancing agents comprises an adjuvant, wherein said adjuvant is Montanide ISA-51, wherein said one or more immune-enhancing agents comprises a cytokine, wherein said cytokine is granulocyte macrophage-colony stimulating factor, wherein one or more immune-enhancing agents comprises a co-stimulatory

molecule, wherein said subject is having or at risk for a post-transplant lymphoproliferative disorder.

The claimed invention is also drawn to a method for eliciting an immune response in a subject, said method comprising administering to said subject (a) an EBV peptide epitope having the amino acid sequence SEQ ID NO: 1, and (b) one or more immune-enhancing agents, wherein said subject expresses one or more HLA class II molecules: HLA-DR1, HLA-DR7, HLA-DR16, HLA-DR52, HLA-DQ2 or HLA-DQ7, wherein one or more immune-enhancing agents comprises an adjuvant, wherein said adjuvant is Montanide ISA-51, wherein said one or more immune-enhancing agents comprises a cytokine, wherein said cytokine is granulocyte macrophage-colony stimulating factor, wherein one or more immune-enhancing agents comprises a co-stimulatory molecule.

Steinman teaches a method for protecting a subject from infection by Epstein Barr Virus (EBV) comprising administering an immunologically effective amount of an immunogenic EBNA-1 polypeptide, which can be a fusion protein of EBNA-1 and a heterologous amino acid sequence, and an adjuvant, acceptable for human, to the subject (page 3, lines 15-18 and 25-27). Steinman teaches processing of EBNA-1 onto MHC class II molecules of dendritic cells (page 9, lines 11-12). The EBV transformed cell lines include HLA-DRw52 and HLA-DRB1) (page 36, lines 9-11). Steinman teaches vaccination effectiveness may be enhanced by co-administration of an immunostimulatory molecule or pro-inflammatory cytokine, such as granulocyte-macrophage0colony stimulating factors with the vaccine (page 33, lines 3-11). Steinman also teaches the prophylactic administration of the vaccine can be used to protect the subject from EBV infection, e.g., to prevent infectious mononucleosis or lymphoproliferative diseases (page

11, lines 5-8). Steinman does not teach SEQ ID NO: 1 (TVFYNIPPMPL) or the adjuvant Montanide.

Moss et al. (hereinafter Moss) teaches cytotoxic T-cell (CTL) epitopes from the Epstein-Barr virus (EBV) latent antigens having the amino acid sequence TVFYNIPPMPL (page 2, line 17-24). Moss teaches a composition for inducing cytotoxic T cells (CTL) in a subject comprising at least one cytotoxic EBV T-cell epitope with at least one pharmaceutical acceptable adjuvant (pages 2-3, bridging paragraph). Moss teaches preparation with several adjuvants but the only one that was found to induce protective CTL was Montanide ISA 720 (page 11, lines 4-21). Moss also teaches vaccines based on full length latent proteins are considered potentially oncogenic and an EBV vaccine based on CTL epitopes derived from latent antigens is currently being developed (page 2, lines 10-15).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the latent antigen sequence as taught by Moss. The person of ordinary skill in the art would have been motivated to make the immunogenic composition with the sequence because Moss teaches it is considered effective, and reasonably would have expected success because Moss teaches vaccines are being developed using EBV latent antigens.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use Montanide as an adjuvant. The person of ordinary skill in the art would have been motivated to use Montanide because Moss teaches it is the only one that induces protective CTL, and reasonably would have expected success because of the teachings of Steinman and Moss. The combination of references teaches the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 24, 2007

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